REMARKS

In the Office Action mailed December 17, 2002, the Examiner rejected Claims 10-17 under 35 U.S.C. § 103(a) as being unpatentable over Danielov et al. (U.S. Patent No. 5,885,974) ("Danielov"). To the extent the rejection applies to the amended claims, Applicant respectfully traverses the rejection.

Applicant respectfully submits that Claims 10 and 14 recite a kit for treating symptoms associated with multiple sclerosis, where the kit includes human growth hormone and at least one supplemental hormone, where the hormones are for establishing a regimen for replenishment of the hormones within a body to physiological levels. Applicant respectfully submits that Danielov does not teach or suggest the desirability of one or more of the limitations recited in Claims 10 and 14.

Danielov teaches delivery across the skin (Danielov, col. 4, lines 16-29), or parenteral administration of compositions for administration to patients suffering from trauma or shock (Danielov, col. 5, lines 15-21). Applicant respectfully submits that it would not have been obvious to adjust the hormone levels as taught by Danielov to render obvious Applicant's invention, since Danielov teaches against adjusting the hormone levels, "Typically, therapeutic agents are administered in such large doses so as to overwhelm the normal biological information transfer system. The therapeutic methods of the present invention differ radically from such dosages in that the compositions utilizing the bioactive agents contain the agents in amounts which are similar to those amounts found in normal living organisms with a normal functioning biological information transfer system . . . amounts ranging from about those found in such normal living organisms to about two or three times the amount found in normal living organisms." (Danielov, col. 8, lines 15-28.) Danielov also teaches that in any case the amount should be less than the buffering amount of the agent (Danielov, col. 8, lines 1-4 and lines 44-47).

Danielov teaches using parenteral administration of an agent for the treatment of hemorrhagic shock (Danielov, col. 13, lines 65-67). An example demonstrating the use of the parenteral administration in conjunction with hemorrhagic shock or experimental traumatization describes lowering the arterial pressure by 30-50% for an animal, for one hour of traumatization, then treating the animals. (Danielov, col. 15, lines 35-50.) During this test, a number of parameters are measured (Danielov, col. 21,

line 10 to col. 22, line 13.) This test used the active agents described in example 12, which achieved a lower mortality rate compared to a standard treatment procedure (Danielov, col. 24, lines 1-14).

Applicant respectfully submits that there is no motivation or suggestion to adapt the treatment for hemorrhagic shock described in Danielov to achieve a kit for treating symptoms associated with multiple sclerosis as recited in Applicant's Claims 10 and 14.

Applicant respectfully requests that the Examiner withdraw the rejection to independent Claims 10 and 14. Applicant respectfully submits that Claims 11-13 are dependent upon allowable Claim 10, discussed above, and are allowable for at least the same reasons, and that Claims 15-17 are dependent upon allowable Claim 14, discussed above, and are allowable for at least the same reasons. Applicant respectfully requests that the Examiner withdraw the rejection to Claims 11-13 and Claims 15-17.

In the Office Action, the Examiner rejected Claims 10-17 under the judicially created Doctrine of Obvious-Type Double Patenting as being unpatentable over Claims 26-34 of U.S. Patent No. 5,855,920. Applicant respectfully traverses the rejection, and respectfully submits that a Terminal Disclaimer disclaiming the terminal portion of any patent granted on this Application has been filed herewith. Applicant respectfully requests that the Examiner withdraw the rejection to Claims 10-17.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "VERSION WITH MARKINGS TO SHOW CHANGES MADE".

CONCLUSION

In view of the foregoing, it is believed that all claims now pending (1) are in proper form, (2) are neither obvious nor anticipated by the relied upon art of record, and (3) are in condition for allowance. A Notice of Allowance is earnestly solicited at the earliest possible date. If the Patent Office believes that a telephone conference would be useful in moving the Application forward to allowance, the Patent Office is encouraged to contact the undersigned at (310) 207-3800.

If necessary, the Commissioner is hereby authorized in this, concurrent and future replies, to charge payment or credit any overpayment to deposit account 02-2666

or any additional fees required under 37 C.F.R. §§ 1.16 or 1.17, particularly, extension of time fees.

Respectfully submitted,

BLAKELY, SOKOLOFF, TAYLOR & ZAFMAN LLP

Dated: 3/17/03

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CERTIFICATE OF MAILING:

I hereby certify that this correspondence is being deposited as First Class Mail with the United States Postal Service in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231 on March 17, 2003.

Nadya Gordon 3/17/03
Nadya Gordon *Date*

ATTACHMENT: VERSION WITH MARKINGS TO SHOW CHANGES MADE

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS

The claims are amended as follows:

10. (Twice Amended) A kit for treating symptoms associated with multiple sclerosis comprising:

human growth hormone; and

at least one of the supplemental hormones selected from the group consisting of sex hormone, melatonin~~,~~ hormone, adrenal hormone, thyroid hormone, and thymus hormone,

wherein the human growth hormone and the at least one of the supplemental hormones is present in an effective amount and in an administerable form for establishing a regimen for replenishment of the human growth hormone and the at least one supplemental hormone within a body to physiological levels.